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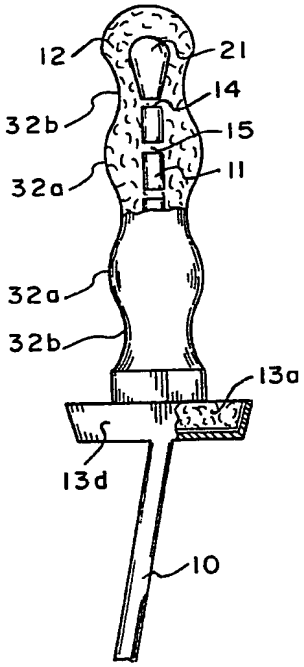
(54) Title: POLYMERIC DRUG DELIVERY APPLICATORS

(57) Abstract

Topical applicators of a porous cellular nature (12) which are primarily designed to be used on the mucous membranes of human or animal body cavities such as the vaginal tract. The invention has particular application to low cost, mass volume, disposable devices pre-impregnated with dry, liquid or semi-liquid therapeutic compositions (102).



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AMENDED CLAIMS
(received by the International Bureau on 11 February 1981 (11.02.81))

1. An applicator for treating a body cavity comprising:
a centrally located core member;
a polymeric foam element of predetermined shape substantially surrounding and being secured to said core member;
said foam element containing between 10 and 60 percent by weight of the foam an additive selected from a group consisting of medicaments, bactericides, antibiotics, germicides, fungicides, spermicides, soaps, detergents and emollients dispersed uniformly therein.

2. An applicator as claimed in Claim 1 wherein said foam element has a densely structured cellular matrix of between approximately 6 to 30 lbs./ft.^{3} and is comprised of normal and abnormal cells, said abnormal cells including ruptured, collapsed, distorted and swollen cells and further including fibrous threads of polymeric material interwoven throughout the cellular matrix thereof.

3. The applicator of Claim 1 wherein said polymeric foam element includes a smooth pliable porous skin surface.

4. The applicator of Claim 1 further including a soluble covering on at least part of the surface of said polymeric foam element.

5. The applicator of Claim 4 wherein said covering is removable from said polymeric foam element.

6. The applicator of Claim 4 wherein said soluble covering includes a medicament therein.

7. The applicator of Claim 4 wherein said soluble covering is comprised of a plurality of layers at least one of which includes a medicament therein and wherein

said plurality of layers are soluble at different rates of time.

8. The applicator of Claim 1 wherein at least part of said additive includes effervescent means.

9. The applicator of Claim 1 wherein at least part of said additive is encapsulated.

10. The applicator of Claim 1 wherein at least part of said additive includes means for time releasing the same.

11. The applicator of Claim 1 including a handle portion extending outwardly from said polymeric foam element and being securely connected to said core member.

12. The applicator of Claim 11 wherein said handle portion is substantially flexible.

13. The applicator of Claim 1 further including an enlarged element adjacent the base of said polymeric foam element and extending transversely thereof.

14. The applicator of Claim 13 wherein said enlarged element is substantially leak proof.

15. The applicator of Claim 1 wherein said core member is substantially hollow and further including a rod-shaped plunger element adapted to be slid into and out of said hollow core member.

16. The applicator of Claim 1 wherein said core member is substantially hollow and further including a plurality of holes passing through the walls of said hollow core member thereby allowing communication between the interior of said hollow core member and said polymeric foam element.

17. The applicator of Claim 16 wherein said core member includes a base adapted to be secured to the open end of a container with said polymeric foam element being located either in said container or extending outwardly away from said container.

18. The applicator of Claim 1 wherein said polymeric foam element is highly hydrophilic, being capable of absorbing up to 25 times its own dry weight of water.

19. A method of producing an applicator for treating a body cavity comprising the steps of:

mixing a polymeric foamable material to obtain a partial polymerized mass;

adding a predetermined additive to said mass, said additive being selected from the group consisting of medicaments, bactericides, antibiotics, germicides, fungicides, spermicides, soaps, detergents and emollients;

mixing said combined mass and additive to substantially evenly disperse said additive;

pouring the mixture into a mold and forming the same into a predetermined shape.

20. The method of Claim 19 including the step of positioning a support structure in said mold to be joined with said polymeric material.

21. The method of Claim 19 further including the step of minimizing foaming during said second mixing step.

22. The method of Claim 19 including the step of encapsulating said additive prior to adding the same to said mass.

23. The method of Claim 19 including the step of coating the outer surface of the polymeric material formed in said mold with a soluble coating material.

24. The method of Claim 23 wherein said coating step includes the step of lining the mold walls with said coating material.

25. The method of Claim 23 wherein said coating step includes the step of preforming a soluble sheath and sliding said sheath over said outer surface.

26. The method of Claim 19 wherein said first mixing step includes mixing a prepolymer urethane resin with a catalyst at 500 to 2500 RPM for 30 to 100 seconds.

27. The method of Claim 19 wherein said second mixing step includes mixing said combined mass and additive at 250 to 1000 RPM for 15 to 100 seconds.

EDITORIAL NOTE

The applicant failed to renumber the amended claims in accordance with Section 205 of the Administrative Instructions.

Original claims 1 to 97 have been cancelled and, accordingly amended claims 1 to 27 are new.

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Published

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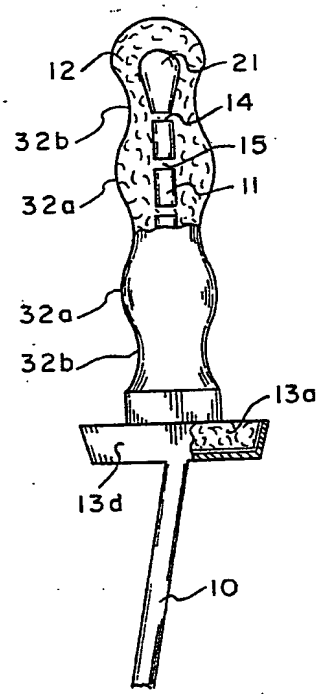
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments

(54) Title: POLYMERIC DRUG DELIVERY APPLICATORS

(57) Abstract

Topical applicators of a porous cellular nature (12) which are primarily designed to be used on the mucous membranes of human or animal body cavities such as the vaginal tract. The invention has particular application to low cost, mass volume, disposable devices pre-impregnated with dry, liquid or semi-liquid therapeutic compositions (102).



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Description

POLYMERIC DRUG DELIVERY APPLICATORS

Technical Field

This invention is directed toward porous cellular topical applicators and more particularly toward the production of such applicators which are smooth-skinned, pre-impregnated and mounted onto a support member in a single operation at considerable savings in production cost and capital investment.

Background Art

A variety of applicators for the dispensing of medicaments have been known or used for some time. Many of these swabbing implements utilize as both the carrier and applicating surface some spongy, hydrophilic material such as polyurethane foam. One such applicator disclosed in U.S. Patent No. 2,170,222 by Strauss consists of a douching swab made of rubber sponge which can be connected to a syringe hose. Means for attaching the sponge to its support member are not specified.

Another patented arrangement described by Leonard et al. is U.S. Patent No. 3,228,398 embodies a cylindrical polyurethane foam sponge applicator secured to an elongated rigid stem by means of a combination of a surgical tape substrate and coatings of glue. In U.S. Patent No. 3,262,450, Elias discloses a smooth-surfaced, topical spongy material for vaginal insertion made of reticulated polyurethane foam with a maximum cell size of 1.5 mm. Another type of applicator disclosed by Fournier in U.S. Patent No. 3,818,911 consists of a pre-moistened vaginal swab machined from cured polymeric foam and shaped in the form of inverted cup-like convolutious for effective removal of debris.

All the foregoing devices utilizing reticulated (i.e. open cell) polyurethane foam as the applicating

surface suffer from a number of physical shortcomings and severe cost disadvantages over the present technology. One such physical shortcoming is caused by the resulting reticulated surface of the machined body of polyurethane foam. No matter how small, the opened cells of such applicators present surface discontinuities which, upon repeated use, can cause friction and irritation on the delicate tissue of the mucous membranes. In contrast, the present technology allows the body of the foam applicator to be covered by a highly porous but continuous skin surface whose smoothness is very close to the human skin.

Another physical shortcoming resides in the fact that the cellular body of all the foregoing applicators has to be machined and treated following a long series of slow and costly operations. Typically, applicators of the type described by Leonard et al. and Fournier have to be produced in the following sequence: Cutting a block of reticulated foam approximating the dimensions of the applicating head; hot-knife machining the block to final shape which may take several intermediate steps depending upon the complexity of the structure; boring the foam head to insert the support stem; placing the adhesive and assembling the parts; smoothing the edges by abrasion; post-impregnating the swab by dip-saturation and drying, if required. Altogether, applicators of this type may require as many as ten manufacturing steps involving a substantial amount of equipment and labor. In contrast, the present technology allows the production of a similar article, smooth-skinned, pre-impregnated and mounted onto a support member in one single operation at considerable savings in production cost and capital investment.

Disclosure of Invention

It is accordingly a primary object of the present invention to provide a polymeric foam applicator and a method of producing the same that will avoid the above

drawbacks of present devices.

It is a further object of the present invention to provide an applicator for the treatment of body or animal cavities having a moist or dry hydrophilic and/or hydrophobic polyurethane foam swab of various densities into which water-active medicaments, soaps, detergents, emollients and combinations thereof can be uniformly and integrally dispersed.

It is a still further object of the present invention to provide a polyurethane foam applicator containing up to 60 percent by weight of medicaments such as bactericides, germicides, antibiotics and the like for use in "prepping" patients or animals undergoing vaginal, cervical, rectal or peri-anal surgery.

It is an even further object of the present invention to dispense any of the foregoing types of medications either through a foam swab or by means of a soluble shell of medications applied onto the surface of the swab or by means of a separate semi-rigid soluble sheath of medications slideable thereon or through a combination of all three methods.

It is a further object of the present invention to provide a means of dispensing medications containing an effervescent agent over a sustained period of time.

It is a still even further object of the present invention to provide a method of manufacture for the various types of applicators and soluble medicated sleeves disclosed herein.

The manner in which the foregoing and various additional objects of the present invention are obtained will become apparent from the following detailed description.

Brief Description of Drawings

For the purpose of illustrating the invention, there are shown in the accompanying drawings forms which are presently preferred; it being understood that the

invention is not intended to be limited to the precise arrangements and instrumentalities shown.

Figure 1 is a front elevational view partly in cross section and partly in phantom of a polymeric applicator constructed in accordance with the principles of the present invention;

Figure 2 is a side elevational view of the device shown in Figure 1;

Figure 3 is a cross-sectional view taken through the line 3-3 of Figure 1;

Figure 4 is an elevational view of a modified form of the invention;

Figure 5 is a cross-sectional view of the device shown in Figure 4;

Figure 6 is a cross-sectional view taken through the line 6-6 of Figure 4;

Figure 7 is a front elevational view of another embodiment of the invention showing the handle in its folded position for packaging;

Figure 8 is a cross-sectional view of the device of Figure 7;

Figure 9 is a cross-sectional view taken through the line 9-9 of Figure 7;

Figure 10 is an elevational view shown partly in cross section of an even further embodiment of the invention;

Figure 11 is a bottom plan view of the device shown in Figure 10;

Figures 12, 13 and 14 are elevational views, partly in cross section, of still further embodiments of the invention;

Figure 15 is a front cross-sectional view of an additional embodiment of the invention;

Figure 16 is a cross-sectional view taken through the line 16-16 of Figure 15;

Figure 17 is an elevational view of a medicated applicator in the form of a therapeutic tampon constructed

in accordance with the principles of the present invention;

Figure 18 is a bottom view of the device shown in Figure 17;

Figure 19 is a cross-sectional view of the device shown in Figure 17 and further demonstrating the use of an inserter;

Figure 20 is a cross-sectional view of a modified form of the device shown in Figure 17;

Figure 21 is an elevational view of an applicator in the form of a disposable douching assembly and shown in its assembled state;

Figure 22 is a cross-sectional view of the device shown in Figure 21 in its packaged condition before assembly;

Figure 23 is an elevational view of a medicated sheath which may be used in conjunction with the device of Figure 21;

Figure 24 is an elevational view, partially broken away, of the device of Figure 21 in combination with a medicated sheath;

Figure 25 is a cross-sectional view taken through the line 25-25 of Figure 24;

Figure 26 is a cross-sectional view of a disposable douching sleeve;

Figure 27 is a bottom view of the sleeve shown in Figure 26;

Figure 28 is a modified form of the douching sleeve shown in Figure 26 and further shown in combination with a douching support;

Figure 29 is a cross-sectional view of the device shown in Figure 28, and

Figure 30 is a cross-sectional view of a mold cavity illustrating the manner in which the various applicators of the present invention may be manufactured.

Best Mode for Carrying Out the Invention

Although functionally and therapeutically related, the various polymeric medicated applicators of the present invention can be classified into three structural groups:

1. Topical swab and surgical applicator for digital handling. (Figures 1-16)

2. Intra-vaginal therapeutic tampon for prolonged body insertion. (Figures 17-20)

3. Manually-handled douching swab implement with medicated sleeve. (Figures 21-29)

As generally shown in Figures 1-16, this type of digital applicator is comprised essentially of two components: a unitary handle-stem structure 10 and 11 equipped toward its mid-section with an optional safety flange 13. Flange 13 provides support for a pre-impregnated polyurethane foam-applicating surface 12 of generally cylindrical shape. In addition, the swab portion 12 of the applicator can incorporate a thin, pliable shell 34 (Figure 15) of absorbable medications either meltable to internal body heat and/or miscible on contact with body fluids. While the swab head is seen to range from two to five inches in length, its diameter should preferably not exceed one inch for human use.

The handle-stem element 10 and 11 can either have a flat or round cross section and it can be made of either plastic, wood or of some paper composition such as twisted kraft, cardboard or plastic reinforced paper. If made of plastic, the structure can either be injection-molded or extruded from such resins as polyethylene, polypropylene, polyester, polyimide or polyphenylene oxide.

Depending upon the chosen material composition, the handle portion 10 can be made rigid and aligned straight with the stem 11 as shown in Figure 12 or angled at 10 to 15 degrees from the normal for self-use convenience (Figures 1 and 2). Or, still further, the handle can be made both flexible and foldable alongside the body of the

swab as shown in Figures 6 and 9. These and other design variances will be described in fuller details below along with the description of specific applicators.

Irrespective of the material used, the stem portion 11 of the structure must incorporate two important physical features essential to the proper functioning of the product. First, if must have foam adhering surface characteristics and it must have a safety tip-searching head combination.

As will be explained in more detail hereinafter, the manufacturing principle of the present applicator involves a two-cavity mold 300 into which the handle-stem element 10 and 11 is secured in a vertical position and around which the uniform reacting mixture is poured. (See Figure 30) Upon curing, the foam solidifies around the stem 11 and takes the shape of the cavity which opens laterally to release the swab assembly. But for the foam to adhere properly to the plastic stem, grippable surface discontinuities of various kinds and preferably perforations through the stem must be provided to eliminate the need for substrate material or for some adhesive requiring additional manufacturing steps.

As shown in Figures 1, 2, 13, 14, 15 and 30, holes 14 incorporated through the foam-supporting structure 11 are particularly desirable as they provide channels for the foamable polymer to flow through during the pouring operation and to solidify into transversal pins or rungs 15 linking both sides of the swab element 12 through the stem portion 11. Alternatively, but preferably in conjunction with perforations, grippable surface discontinuities could take the form of circular grooves 16, annular ridges 17 or notches 18 as shown in Figures 1 and 2, or any number of variations thereof such as lugs or threads (not shown). For example, the paper-composition stems 11a of Figures 10 and 12 incorporate on their surfaces dimples 19 or knurls 20. Still further, the stem-support element of Figures 5 and 8 could be in the

form of an extruded and flexible hollow straw 11b whose bellows-like surface discontinuities 24 provide an appropriate grip for the foam sheath to adhere to and to act as a handle.

The second important design aspect of the device lies in a combination safety tip and searching head surmounting the distal end of the stem 11 for the dual purpose of preventing internal injury and to help facilitate passage through sphincter muscles. As shown in Figures 1, 2, 14 and 15, the integral end-portion 21 of such flat support stems are rounded or bulbous shaped and are positioned relatively close to the outer edge of the swab to prevent the foam from "bunching out" at the point of insertion. Alternately, injection molded tips can be shaped in the form of a flared cup 22 shown in Figure 13, while other rod-like support structures such as those of Figures 5, 8, 10 and 12 are separately fitted with a round or semi-spherical tip 23 of rubber or soft plastic.

As will become apparent, the particular polymer technology of the present invention allows the foam head to be made in virtually any shape and with a highly permeable skin for liquid absorption or diffusion. The configuration and surface characteristics of the swab can therefore be "tailored" to the specific requirements of any therapeutic application, particularly those of an internal nature.

For example, swabs primarily designed to scoop out debris or undesirable secretions are shown in Figures 4 through 9. The swab element of Figures 4 and 5 is comprised of a cylindrically shaped body 12 of uniform diameter with a rounded or oviform top for easy insertion into body or animal cavities. Mechanical scrubbing is accomplished by means of a plurality of semi-circular annular grooves 25 regularly spaced along the length of the swab and into which debris can accumulate for removal.

In the swab design of Figures 8 and 9, the scooping

action is enhanced further by having a similar series of annular troughs 25a separated by concave sections 26 terminating in soft, pliable fins 27. As the swab is being manipulated up and down a cavity, the pliable fins 27 are designed to penetrate into the folds of the canal and to exert thereon a gentle scraping action in both directions scooping debris into the troughs 25a.

In the designs shown in Figures 4 through 9, the safety flange 13a is made of foam and is integral with the swab element 12. The handle section 10a is also covered by a sheath 10b of the same foam so that the swab element 12, flange 13a and their handle form a unitary foam construction around the central supporting structure. Due to the inherent flexibility of the straw and foam composition of the handle 10a, it can be conveniently folded upwardly at 180 degrees as shown in Figures 8 and 9. For packaging convenience, the handle element 10a can be snapped folded and held into a compliant and cooperating open cavity 28 provided on the side of the flange 13a as shown in Figures 6, 7, 8 and 9.

Swab configurations shown in Figures 10 and 12 are designed for situations where a softer scrubbing action is indicated. Referring to Figures 10 and 11, the cylindrical foam applicator 12 incorporates a series of annular V-shaped recesses 25b forming lateral notches 31 whose depth can range from two to five millimeters depending upon the desired effect. Similarly, the frequency of these annular recesses can also vary from two to four per inch depending upon the desired degree of mechanical cleansing.

Alternately, the scraping edges can also be gently contoured to reduce friction. As shown in Figure 12, the swab element 12 consists of a series of superposed, truncated triangular sections 29 with a rounded base forming a series of slanted scales 31a whose depth and frequency can be made to vary as desired.

In still another class of applicators where

absorption or drug release are preferred over scrubbing ability, the foam swab is made to assume a smoother and/or shallower profile as shown in Figures 13 through 16. In Figure 13, the swab is made up of a series of superposed concave sections 30 creating at their points of junction a corresponding series of conical scraping edges 31b. In this embodiment, the flange arrangement differs somewhat from the previous applicators in that it is comprised of two superposed flange thicknesses: a flat flange support 13c integral with the plastic molded handle 10 and a foam flange 13a integral with the swab element 12.

In another configuration shown in Figure 14, the swab is composed of a series of alternating convex and concave sections 32a and 32b eliminating the formation of scraping edges. This embodiment shows still another variance of the safety flange. The plastic handle 10 incorporates a circular trough 13d in the order of one and a half inches in diameter housing a foam base 13a integral with the swab element 12. The advantages of such flange arrangement are two-fold: a) First, in case of dripping during insertion of the swab, excess fluid is collected by the combination foam flange 13a and leak-proof plastic receptacle 13d; b) Second, the rigidity of the flange structure guarantees that the swab cannot be pushed into any body cavity beyond a given level which is a beneficial feature for consumer applications.

In another embodiment shown in Figures 15 and 16, the body of the generally cylindrical swab 12 is composed of a series of truncated spheres 33 superposed on top of each other and forming one integral body of foam secured to the stem 11. Contiguous with the base of the swab 12 (but not integral therewith), the applicator incorporates a circular and concave safety flange of a still different structure yet similar in concept to the one shown in Figure 14. Composed of a highly absorbent grade of polyurethane foam to soak up

excess fluid from the inserted swab, the foam flange 13e is encased in a pre-formed trough 13f of thermoformable plastic such as vinyl, polyethylene, latex or even coated paper. To accomplish a similar result, the base of foam flange 13a in Figures 10 and 12 could be sprayed after molding with some water-proof compound including such materials as latex, neoprene, natural rubber, waxes or the like. In this particular applicator, the foam composition of the swab 12 is different from the foam composition of the flange element 13e and each foam element, even though molded separately, can be cast in sequence in the same mold.

The applicator shown in Figures 15 and 16 also differs from the previously described devices in that it includes a medicated shell 34 surrounding the foam swab 12. This applicator is preferably manufactured in the following manner.

Step 1. The pre-formed flange 13f and medicated shell inserts 34 (not shown) are positioned into the open mold as shown in Figure 30. While the flange inserts are pre-formed preferably from thermoformable materials, the medicated shell 34 can be made in several ways: a) its ingredients can be pre-cast into a smooth, pliable cylinder and inserted into the closed cavity; b) the ingredients can be hot-sprayed onto the open surfaces 301d and 301b of the cavity; c) the ingredients can be brush-coated thereon; d) or a flat sheet of ingredients can be press-fitted into each half of the open cavities.

Step 2. The handle-stem element 10 and 11 is inserted vertically into the closed cavity and locked in at the proper level.

Step 3. Foam #1 mix comprised of liquid resins and medications added prior to foaming is poured into the closed cavity.

Step 4. The foam is allowed to rise and to jell into swab element 12. If a pre-cast cylindrical shell 34

of medications is used, the internal pressure exerted by the rising foam will force the sides of the cylinder against the walls of the cavity, thereby shaping it into the same configuration as the swab element. Irrespective of the way the shell ingredients are applied to the cavity, they will intimately adhere to the surface of the swab.

Step 5. A highly hydrophilic foam mix #2 is then poured into flange cavity 13f.

Step 6. The foam is allowed to rise and to jell into solid flange 13e.

Step 7. Cavities may be opened to release the swab assembly with its medicated shell.

As will become apparent hereinafter, the foregoing methodology also applies in part or in whole to the therapeutic tampon of Figures 19 and 20 and to the douching sleeve of Figure 26. However, the shell coating could be alternately applied to the foam element by dipping it into a bath after molding. It should also be apparent that more than one shell 34 could be employed and that each shell layer could be comprised of the same or different medication and having the same or different solubility characteristics.

While a generally cylindrical swab is deemed best suited for any microbicidal applicator to sterilize such areas as the cervix, vaginal vault, perineal and ano-rectal areas, it should be understood that the foregoing embodiments need not be solely confined to cylindrical or tubular shapes. Although not shown, topical foam swabs could assume any number of shapes and/or geometries without departing from the polymer technology of the present invention.

The structure of the foregoing embodiments for topical swabs have been modified into a novel concept for an intra-vaginal therapeutic tampon for the treatment of moniliasis, trichomonasis, cervicitis and other non-specific vaginal disorders. Normally, these disorders

require frequent internal applications of soluble cream-based or gelatin-based medications in suppository form which, upon melting, drip, cause soiling and discomfort.

By capitalizing on the drug-carrying and drug-release properties of the present foam technology to be described in more detail below, a much improved mode of treatment has been developed with the following advantages:

1. Greater surface contact between medications and diseased mucous surfaces.
2. Sustained drug release over a controlled period of time.
3. Decreased number of applications per day.
4. Greater comfort and mobility for the user.
5. No bypass, leak-proof.

Referring to Figures 17 through 20, the therapeutic tampon is comprised of a series of superposed truncated spheres 102 forming one integral body of foam 101 of generally cylindrical shape. While some degree of surface discontinuity is desirable from the standpoint of anatomical conformity, the tampon element 101 could assume a perfectly smooth cylindrical shape without affecting the drug release properties of the foam.

The base of the applicator 101 is comprised of two or more rings 103 of foam substantially larger in diameter than the body of the tampon. Rings 103 are designed to exert pressure against the vestibule of the vaginal canal and to act like the gaskets of a plug to prevent by-pass of the melted medicaments. In addition, the external surface of these rings is sheathed with a pre-formed layer 104 of flexible, water-proof material such as vinyl, latex, wax or polyethylene. Alternately, the base of the tampon could be dip-coated or spray-coated with similar leak-proof compounds.

Insertion and retrieval of the tampon can be accomplished in two different ways depending upon the

internal construction of the device. As shown in Figures 18 and 19, one embodiment is comprised of a central tubular core 105 of semi-rigid material made from polyurethane, nylon, latex or paper-coated laminates. The tubular core 105 extends almost through the entire length of the tampon and incorporates an axial, internal bore 106 of substantially the same length. The diameter of the bore 106 is in the order of five to seven millimeters and allows the rod-like plunger 107 of a reusable inserter 110 to be introduced therein to position the tampon into the vaginal cavity. Once the tampon is in place, the plunger 107 is slid out and removed.

Two safeguards are provided against perforations. First, a flange 109, integral with the inserter 110, is designed to push up the tampon from the base of its semi-rigid core 105 while the plunger 107 exerts a simultaneous push from the upper portion of the tampon. Since both elements are displacing the tampon at the same rate, perforation from the plunger is made impossible by the position of the flange against the base of the axial core 105. In addition, the uppermost portion of the tubular core 105 incorporates an extension of solid material 108 as reinforcement against the tip of the plunger.

This type of therapeutic tampon comes equipped with a set of recall strings 111 tied around the base of the tampon just above the neck of the enlarged leak-proof rings 103 as shown in Figure 17. These recall strings 111 are used to withdraw the device similar to any commercial type of catamenial tampon. Alternately, the recall strings 111 can be incorporated in the mold for the polymeric material of the core 105 and allowed to extend from the base of the tampon.

Another embodiment shown in Figure 20 incorporates a solid, axial and rod-like core 112 of semi-rigid, non-breakable material extending substantially through

the entire length of the body of foam 101. While the generally cylindrical foam portion of the tampon can assume any number of surface features, the core element 112 should preferably be made of polyurethane, elastomer, nylon, latex, polypropylene, or combinations thereof.

In addition to a plurality of leak-proof, gasket-like rings 103 described earlier, the bottom section of the tampon incorporates a semi-spherical cavity 113 through which protrudes the tail-end of the core element 112 shaped in the form of an integral loop 114. While the user can grasp through the open cavity 113 the lowermost section of the polymeric core 112 and utilize it as means of inserting the tampon, the recall loop 114 serves the purpose of withdrawing the device.

The basic concept of the topical foam swab as a carrier and applicator of water-active drugs has been expanded further to a douching swab implement with or without a soluble sheath of medications as generally shown in Figures 21 through 25. Alternately, the drug carrier could be a disposable sleeve of medicated polyurethane foam slideable over a douching tip shown in Figures 26 through 29.

Referring more specifically to Figures 21 and 22, the douching swab assembly comprises a body of highly porous foam 201 centered over a plastic douching tip 202 incorporating a plurality of exit holes 205 for the douching liquid. To help secure the foam to its plastic support, a series of annular knurls 203 and saw-tooth fittings 204 are incorporated into the tip. The douching tip 202 is connected through a flared neck 206 to a reversible screw cap 207. For packaging convenience and space economy, such cap allows the douching swab element 201 to be screwed upside down into the empty douching container 208 and is sealed on its opposite open side by means of a peel-off strip of foil 209. The douching container could be either a squeeze-type blow-molded bottle or a collapsible bladder of plastic film or

laminate.

To assemble the douching element, the foil 209 is removed and the douching swab is inverted and screwed onto the top of its container 208 which has been previously filled with water. (See Figure 21) Upon squeezing the container, the water oozes out through the swab along with the medicaments. These medicaments can be admixed to the water in powdered or liquid concentrate form. Alternately, they can be pre-impregnated into the douching swab foam 201 or incorporated as a soluble shell to the surface of the swab. Even further, they can be delivered by means of a semi-rigid sheath 210 slideable over the douching swab 201 and soluble to body heat and/or douching liquid as shown in Figures 23, 24 and 25. To speed the liquefaction of the medicated sheath 210, small perforations 211 can be provided over its surface so that both internal and external sides of the sheath can be subjected to water contact from the douching nozzle.

As shown in Figures 26 through 29, a more economical alternative to the foregoing douching embodiment is comprised of a disposable sleeve of porous foam 212 incorporating a thin outer shell 213 of soluble medications and slideable over a reusable plastic douching tip 214. As described for the previous swab embodiments, the body of the foam sleeve 212 can incorporate any number of surface features, such as superposed concave sections 215. While the liquid forced through the holes 205 of the douching tip 214 will ooze out through the sleeve along with the medicaments, these medicaments can also be diffused either from the pre-impregnated foam sleeve 212 or from the soluble shell 213 which can be incorporated to any desired extent over the surface of the applicator. More specifically, the shell can cover the entire applicator as shown in Figure 19, or only a part thereof such as shown in Figure 26.

It can be seen from these descriptions that the

foregoing douching swab embodiments are therefore capable of achieving a triple therapeutic action, hydraulic, mechanical and medicinal, which is deemed to be most beneficial for a substantial number of vaginal disorders.

As should now be readily apparent from the foregoing description, the unique characteristics of the polyurethane technology of the present invention are applicable to a variety of medicated applicators for body cavities. These applicators differ markedly from the prior art from the combined standpoints of internal structure, polymeric composition, release of pre-impregnated medications and manufacturing method. In a more precise way, the core of the technology and of its present product applications resides in the ability of producing a generally cylindrical body of foam or tubular swab element capable of incorporating at least nine distinct features:

1) The polymeric swab element can be integrally and permanently bonded to a variety of internal supporting structures during the molding operation which obviates the need for substrates, primers, adhesives or any other external devices.

2) The polyurethane swab is inherently covered with an extremely smooth, thin and pliable skin which is highly porous to the absorption of body fluids and/or to the diffusion of liquid medications.

3) The polyurethane foam is highly hydrophilic and is capable of absorbing up to 25 times its own weight of liquids.

4) The polymeric swab can be cast in a mold into virtually any shape over any kind of support which eliminates a large number of costly and time consuming manufacturing steps.

5) The foam swab can be pre-impregnated by as much as 60 percent by weight with almost any desired combinations of chemicals and/or medications activatable by internal body heat, water contact or body fluids.

6) The swab element can be intimately coated with a

solid or semi-solid shell of absorbable medications either meltable to internal body heat and/or miscible on contact with body fluids. The shell can be comprised of several thin layers of identical medications releasable over a period of time while the swab carrier can be pre-impregnated with a different medication for secondary treatment of diseased mucous or skin surfaces.

7) The various chemicals and medications admixed to the foam can be encapsulated for controlled release action.

8) The medications diffused from the foam can be made to effervesce for better penetration into the crypts and folds of certain body cavities.

9) Any or all of the above characteristics can be imparted to the swab element in one single molding operation at considerable savings over existing conventional manufacturing methods.

Depending therefore upon the chosen type of internal structure, mode of handling and medical additives, the foam swab can be adapted to an equal variety of products for specific medicinal treatments. For example, fitted with a stem-handle support such as shown in Figures 1-16 and pre-impregnated with a germicide, the foam swab can be used as a "swabstick" for medical, surgical or veterinary applications. Fitted with a flexible core and an appropriate inserter, such as shown in Figures 17-20, it can be made into a vaginal or rectal tampon for the treatment of various disorders. And attached over a douching tip, the foam element can be turned into a douching swab for routine or therapeutic feminine hygiene as illustrated in Figures 21-29.

The foregoing internal and external physical characteristics of the foam swab result from the structural arrangement of the cellular matrix which is composed of collapsed, ruptured, stretched, distorted, reticulated and swollen cells as well as normal cells. Randomly, interspersed throughout the cellular structure

are fibrous threads or filaments caused by a particular over-stirring of the foamable polymers which increase the structural strength and resiliency of the foam. Although three to six times as dense as commercial polyurethane foam produced by existing methods, the cellular material of the present invention which has a densely structured cellular matrix of 6 to 30 lbs./ft.^{3} is easily wetted and readily discharges the pre-impregnated additives upon gentle pressure or even upon weak internal muscular action.

The preparatory procedure found most suitable utilizes a first mixing operation to obtain a partially polymerized mass and one or more additional mixing operations to regulate the consistency and viscosity of the polymeric mass during which medicaments or other additives are dispersed therein. It is essential, however, that the first mixing step be performed in the absence of additives which interfere with the foam-making reactions.

In the first mixing step, prepolymer urethane resin is admixed and reacted with a catalyst at 500 to 2500 RPM for 30 to 100 seconds to produce the partially reacted polymeric mass. The prepolymer resin may be prepared from polypropylene glycol and toluene diisocyanate according to known technology or they may be purchased commercially. Regardless of the source, the prepolymer resin to be used in the production of the foam swabs should have the following characteristics: a Brookfield viscosity at 25°C between 5000 and 15,000 CPS, preferably between 7200 and 9400 CPS; an isocyanate content (NCO) between 6 and 12 percent; a hydroxyl number ranging from 40 to 80 but preferably between 50 and 60 and a molecular weight of the polyol component ranging between 1800 and 4000. Among others, two types of commercially available prepolymer resins may be used in the above procedure. These are A) STEPAN F-202 and WITCO L-128; B) GRACE 2001 and 3001.

The first type such as polyether prepolymer F-202 manufactured by Stepan Chemical Company requires the addition of 1.5 to 5.0 percent by weight of a catalyst consisting by weight analysis of 18 to 22 percent triethanolamine, 10 to 15 percent triethylenediamine and 60 to 70 percent water.

The second type is preformulated by the manufacturer in a manner that requires the addition of water only to start the reaction and to obtain a foamable mass. Examples of such prepolymer resins are HYPOL 2001 and 3001 manufactured by W. R. Grace Chemicals which require, according to the manufacturer's recommendations, the addition of between 30 to 120 parts of water per 100 parts of prepolymer resin. In either case, the catalyst system may also include between 0.5 and 2.0 grams of cell modifier such as polydimethylsiloxane or the equivalent per 100 grams of prepolymer resin.

The polymeric mass can also be prepared directly from prepolymer precursors and catalysts by employing the procedure generally known in the art as the "one step" method and incorporating therein the proprietary techniques used during the final stages of the mixing procedure.

Because mixing is performed at a low speed for a longer period of time than is typical of the prior art, the reaction is retarded and active foaming has not as yet started at the end of this first mixing period. However, chemical changes have occurred which alter the viscoelastic characteristics of the starting materials. Consequently a partially reacted polymeric mass is formed whose viscosity and density are sufficiently high to allow incorporation of the medicaments without deleterious effect on subsequent polymerization. Properly prepared, the polymeric mass has a creamy consistency and shows little evidence of foaming.

The range of medicaments which may be dispersed within the polyurethane body of foam in the foregoing

manner is quite extensive and depends upon the particular use intended. The additives may be particulate solids, ointments or miscible and immiscible liquids. Active ingredients such as bactericides, germicides, and antibiotics can be used for the treatment of abnormal vaginal conditions such as moniliasis, trichomonasis and other non-specific types of vaginitis. Other formulations are also possible for use by physicians to "prep" patients prior to vaginal, cervical or peri-anal surgery. Soaps, detergents, emollients, fragrances and even colors can be used to prepare applicators for use in general feminine hygiene. In many instances these additives would also be included in foam applicators for specific purposes as inert carriers of the active compound. Table I lists and identifies commercially available medicaments and additives which may be incorporated into the foam in recommended dosages.

Dry additives and additives in ointment form which are to be dispersed within the polymeric mass are preferably premixed to obtain a uniform composition. Because liquid medicaments are easily dispersed within the polymeric mass, they may be either premixed with the dry additives or introduced directly into the polymeric mass at any time during the second or subsequent mixing steps, but at least 15 seconds prior to the termination of mixing to ensure complete and uniform dispersion.

The second mixing step, which is performed at 250 to 1000 RPM for 15 to 100 seconds, preferably at 400 to 700 RPM for 30 to 80 seconds, not only serves to disperse the additives within the polymeric mass to obtain a uniform reacting mixture, but also regulates cell formation. The agitation disperses evolved gases which are necessary for foaming of the polymeric reactants. Hence, active foaming is minimized. The agitation produces shear forces that tear or shred a portion of the cells formed during this step. Thus, the finished applicator head, when observed under a microscope, contains

fibrous threads of polymerized polyurethane interwoven throughout the cellular matrix.

Longer mixing promotes polymerization in the absence of foaming and yields denser, more fibrous structures. If mixing were not prolonged as taught by the present invention, the uniform reacting mixture would not attain the density necessary to support the weight of the medicaments. The mixture would begin to foam and then collapse. If the first mixing step were extended until the viscosity and density were sufficient to allow incorporation of the medicaments, the polymeric mass would then be too viscous to work properly, and the medicaments would not be distributed uniformly.

The shear forces of the second mixing step also create large numbers of distorted, collapsed and stretched cells. Many of these cells, even those forming the skin of the final applicator head, are hydrophilic in nature, and allow water to enter and to dissolve the medicaments contained therein. Thus, the foam applicators do not require a highly reticulated surface for the release of the additives. At the end of the second mixing step, the twice-mixed polymeric mass, i.e. the uniform reacting mixture, is ready to be molded to the proper swab configuration.

The foam applicator is made by pouring the uniform reacting mixture obtained by the foregoing procedure into a closed two-cavity mold containing the desired supporting structure. (Figure 30) The mold is desirably constructed of two mating sections operating laterally against each other to allow the reacting mixture to be poured in and to release the finished applicator assembly. The polymeric mix is sufficiently fluid to conform exactly to the shape of the cavities as it begins to foam. Of particular importance, the foaming material can also penetrate holes and surround intricate surface discontinuities thereby forming an integral bond between foam and support. While the foaming material is densified by expanding in a

close mold, the finished body of foam is soft, pliable and can readily absorb and release water or body fluids.

Although the release of the added ingredients is slower and more linear than in conventional bodies of foam, substantially longer use can still be obtained by encapsulating, in part or in whole, medicaments and other additives. Encapsulation can be achieved by two methods. In the first method, a previously prepared body of foam containing additives is shredded or comminuted to between 20 to 100 U.S. Standard Sieve and then blended into the partially reacted mass during the second mixing stage. Although all of the additives may be encapsulated by this method, it is most useful where only a liquid additive, typically an emollient, is to be coated, or where a mixture of emollient and dry additives could not be encapsulated effectively in any other way.

The second method encapsulates the additives, either individually or in combination with one another with a water soluble film using a film forming material such as polyvinyl alcohol, polyvinyl pyrrolidone, hydroxymethyl cellulose, polyvinyl methylether, polyacrylamide or Triton X-100. An atomized mist of a 1 to 5 percent aqueous solution of the film former is sprayed onto the additive(s), and the moisture is allowed to evaporate therefrom. This operation may be carried out in a tumble dryer or fluidized bed dryer with warm air used for drying. The treated additives are then comminuted to between 60 and 100 mesh and added to the partially reacted mass in the second mixing step. The second method is preferred for dry additive mixtures that do not tend to clump or agglomerate. These and other characteristics of the polymeric foam will be made even more apparent with the examples of the various formulations and preparatory steps described below.

While a specific preferred molding technique for the applicator is described above, substantially any known process may be used for forming the shells and

sheaths utilizing, for example, the formulations set forth in Table I. Among other techniques, the shell may be precast into a cylindrical shape, the shell ingredients may be sprayed or brushed onto the mold walls or flat sheets of material may be press-fitted onto the mold walls. It would also be possible to dip-coat the applicator after it is molded. The sheath is preferably cast into its desired shape.

To achieve various rates of dissolution (with respect to time), the glycol bases of the shell or sheath can be varied in composition. A lower melting point is accomplished by decreasing the amount of higher molecular weight glycols whereas, to achieve higher melting points, the amount of higher molecular weight glycols is increased. The proportions for incorporating water and medications to the glycol base are as follows:

Polyethylene glycol 6000	50%
Polyethylene glycol 1500	30%
H_2O Purified and Medications	20%

Theobroma oil (cocoa butter) can be used as a carrier of medications for the shell and sheath. This can be prepared by melting the Theobroma oil and by intimately incorporating into it an equal amount of medicaments by weight. The rest of the required amount of Theobroma oil is then admixed to the melted liquid. The ingredients are then cooled down to almost the desired melting point, uniformly mixed and poured into chilled cavities to cast either a shell or sheath. The melting range of Theobroma oil of 30 to 35°C can be increased by the addition of white wax. Other carriers may be polyethylene derivative of sorbitan monostearate (Tween 61 by Atlas Chemical), polyoxyethylene 30 stearate (Myrj 51 by Atlas Chemical) or polyoxyl 40 stearate (Myrj 52 by Atlas Chemical).

Furthermore, either the shell or the sheath structure can be composed of several heat-meltable layers of the

same medications in addition to the pre-medicated body of foam. Such arrangement guarantees a prolonged medicinal action particularly useful for therapeutic tampons. In effect, depending upon the chosen composition, a fresh layer of medications can be dissolved for absorption approximately every hour or so.

The present technology also allows for the production of therapeutic tampons incorporating two different medications to be applied in sequence which is sometimes required for certain specific vaginal disorders. For example, such a tampon could comprise a partial outer layer of quickly dissolving cocoa butter to facilitate passage and insertion in the vaginal tract. This outer layer could be followed by two or more full-length inner layers of medications. Once the shell layers are fully dissolved, a different medication pre-impregnated in the foam could come into effect activated by either body heat and/or body secretions.

Examples of various formulations for the manufacture of applicators in accordance with the present invention are set forth in Table I attached hereto. Each of the seven columns under the heading "Foam Swab" in the table corresponds to a specific formulation for a swab. Similarly, each of the six columns under the heading "Shell and Sheath" corresponds to a specific formulation therefor. In order to further illustrate the various applications of the present invention, set forth below are several specific examples which are taken from Table I.

EXAMPLE I. (Column 2 ingredients)

A topical swab such as illustrated in Figures 1-14 for the treatment of trichomonas is made from the following compositions:

Formula A		
Diiodohydroxyquin	0.1	gm
Sodium Lauryl Sulfate	0.5	gm
Phenyl Mercuric Acetate	0.003	gm
Papain	0.020	gm

Formula B		
Hypol 3001	3.0	gm
H_2O Purified	3.0	ml
Tegostab B.F 2270(Goldschmidt)	0.1	gm

The ingredients of Formula A are first thoroughly mixed. With respect to Formula B, the 2270 silicone is first added to the resin. Thereafter, the water is added and these ingredients are mixed rapidly until foaming is initiated. At this point the ingredients from Formula A are added and the entire solution is mixed rapidly and poured into the mold.

EXAMPLE II. (Column 7 ingredients)

A surgical swab-stick (germicidal) such as shown in Figures 5-16 or an iodine douching swab or sleeve such as shown in Figures 21-29 for patient prepping or for therapeutic douching for vaginitis is prepared from the following formulation:

Hypol 2001	6.0	gm
H_2O Purified	6.0	ml
Povidone-Iodine (powder)	0.006	gm
Tegostab 2270	0.6	gm

The tegostab is first added to the resin followed by the water. These ingredients are mixed until foam begins to rise or begins to expand. At this point, the povidone-iodine powder is added and the mixture is stir-mixed for three to five seconds before being poured into a mold. For topical use, the povidone-iodine powder may be adjusted to .075 to 1 percent of available iodine.

EXAMPLE III. (Column 6 ingredients)

A vaginal cleanser such as shown in Figures 5-14 or a douching sleeve (without a shell) such as shown in Figures 26-29 is formulated as follows:

Formula A	Swab	Douching Sleeve
Hypol 2001	6.0 gm	6.0 gm
H_2O Purified	6.0 ml	6.0 ml
Tegostab 2270	0.6 gm	0.6 gm

Formula B	Swab	Douching Sleeve
NACL	0.06 gm	2.25 gm
Disodium Ededate	0.0003 gm	0.0012 gm
Sodium Lauryl Sulfate	0.15 gm	0.60 gm

The tegostab is first added to the water and this mixture is added to the resin and stirred until foam begins to expand. The ingredients of Formula B are then blended thoroughly and added to Formula A. The entire solution is then stirred rapidly and poured into a mold.

EXAMPLE IV. (Column 1 ingredients)

A foam sleeve for effervescent douching such as shown in Figure 28 for routine feminine hygiene is formulated as follows:

Prepolymer F 202	50 gm
Catalyst	1.25 gm
Sodium Lauryl Sulfate	0.50 gm
Citric Acid	20.0 gm
Sodium Bicarbonate	10.0 gm
Polyethylene Glycol 1000	7.5 gm
Polyethylene Glycol 4000	2.5 gm

The glycols are first blended on a water bath until liquid and clear. The citrate and bicarbonate are then added and stirred into the glycols until solidified. This solidified mass is chilled and granulated to about 40 to 100 mesh. The prepolymer F 202, catalyst and sodium lauryl sulfate are rapidly mixed. When foaming begins, the granulated mix is added, stirred for about three to ten seconds, and poured into molds. The preferred catalyst for this formulation is comprised of H_2O 66.6 percent;

triethanolamine 20.8 percent; triethylenediamine 12.6 percent.

EXAMPLE V. (Column 8 ingredients)

A medicated shell for an antifungal tampon illustrated in Figure 19 for the treatment of vaginitis is prepared using the following formulation:

Formula A	
Hypol 2001	3.0 gm
Water Purified	3.0 ml

Formula B	
Polyethylene Glycol 4000	1.1 gm
Polyethylene Glycol 400	0.6 gm
Stearyl Alcohol	0.1 gm
Clotrimazole	0.02 gm

The ingredients of Formula B are first thoroughly mixed. The water and prepolymer are then combined and stirred until the foam starts to rise. The ingredients of Formula B are then added, stirred rapidly for about five seconds and poured into a mold.

EXAMPLE VI.

A medicated therapeutic tampon including a shell such as shown in Figure 19 for the treatment of trichomonas vaginalis, monilia (candida albicans) and haemophilus vaginalis is produced utilizing three separate formulations: One for the shell and two for the tampon per se.

A. Shell Formula (Column 13 ingredients, single unit)

Polyethylene Glycol 4000	0.7 gm
Polyethylene Glycol 400	1.2 gm
Stearyl Alcohol	0.1 gm
Furazolidone	0.275 gm
Nifuroxime	0.4125 gm

The polyethylene glycols and the stearyl alcohol are heated to about 65°C and stirred. The furazolidone and nifuroxime are subsequently added, thoroughly mixed and poured into a shell mold and chilled.

B. Tampon Formula (Column 5 ingredients, 100 units)

Polyethylene Glycol 4000	120	gm
Stearyl Alcohol	80	gm
Furazolidone	30	gm
Nifuroxime	45	gm

The polyethylene glycol and stearyl alcohol are heated in a water bath to about 65°C and mixed. After blending, the remaining ingredients are added and thoroughly mixed. The resulting mixture is then cooled and chilled until solid. This solid mass is granulated to a range of 40 to 100 mesh.

C. Tampon Formula (Column 5 ingredients, single unit)

Granulated Mix (as per B above)	2.7	gm
Hypol 2001	3.0	gm
H_2O Purified	3.0	ml
Tegostab B.F 2270(Goldschmidt)	0.1	gm

The tegostab is first added to the resin and then combined with the water. These are rapidly mixed until foaming has started at which time 2.7 gms of the granulated mix from Formula B above is added. This is stirred rapidly and poured into a mold.

The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof and accordingly reference should be made to the appended claims rather than to the foregoing specification as indicating the scope of the invention.

TABLE I. FORMULAE

(in grams and milliliters)

Ingredients	Manufacturers
Prepolymer F 202	Stepan
Hypol 2001	Grace
Hypol 3001	Grace
Water - Purified (ML)	*
Polyethylene Glycol 400	*
Polyethylene Glycol 1000	*
Polyethylene Glycol 4000	*
Gelatin - USP Granular	*
Glycerin - USP	*
Allantoin	*
Oxyquinoline Sulfate	*
Disodium Ededate	*
Lactose	*
Aminacrine Hydrochloride	*
Sulfanilamide	*
Sodium Alginate	*
Methyl Paraben	*
Diiodohydroxyquin	*
Sodium Lauryl Sulfate	*
Phenyl Mercuric Acetate	*
Papain	*
Calcium Citrate	*
Silicone - Tegostab 2270	Goldschmidt
Stearyl Alcohol	*
Furazolidone	*
Nifuroxime	*
Clotrimazole	*
Citric Acid	*
Sodium Bicarbonate	*
Boric Acid	*
Ammonium Alum	*
Tyrothricin	*
Sodium Chloride	*
Povidone - Iodine	*
Catalyst	*

TABLE I. FORMULAE (continued)

Foam Swab Formula Number

	1	2	3	4	5	6	7
	50						
5				3	3	6	6
		3	6				
		3	6	3	3	6	6
	7.5						
10	2.5				120		
				.002			
15				.0004		.0003	
				.01			
20							
		.1					
	.5	.5		.135		.15	
		.003					
		.020					
25							
		.1	.1	.1	.1	.6	.6
					80		
					30		
					45		
30							
	20						
	10						
			.3				
			.2				
35							
						.06	
							.006
	1.25						

TABLE I. FORMULAE (continued)

Shell and Sheath Formula Number					
8	9	10	11	12	13
3					
3	2.1	24			
.6					1.2
			4.5	4.4	
1.1			1.5	.2	.7
	24				
	50	1.5			
	1.7	4	.15		
	.2	.04	.15	.003	
	12	6	1		
		1.2			
		.08			
				.003	
		.02			
.1					.1
					.275
					.412
.02					
				.0025	

Claims

1. A medicated applicator comprising:
a centrally located core member, and
a polymeric foam element of predetermined shape substantially surrounding said core member, said foam being pre-impregnated with a preselected medicament.

2. The applicator of Claim 1 wherein said polymeric foam element includes a smooth pliable skin surface.

3. The applicator of Claim 2 wherein said surface is porous.

4. The applicator of Claim 1 further including a soluble covering on at least part of the surface of said polymeric foam element.

5. The applicator of Claim 4 wherein said covering is integral with said polymeric foam element.

6. The applicator of Claim 4 wherein said covering is removable from said polymeric foam element.

7. The applicator of Claim 4 wherein said soluble covering includes a medicament therein.

8. The applicator of Claim 7 wherein the medicament contained in said soluble covering is a different medicament from said preselected medicament pre-impregnated in said polymeric foam element.

9. The applicator of Claim 4 wherein said soluble covering is comprised of a plurality of layers.

10. The applicator of Claim 9 wherein at least one of said layers includes a medicament therein.

11. The applicator of Claim 9 wherein said plurality of layers are soluble at different rates of time.

12. The applicator of Claim 1 wherein said core member is integral with said polymeric foam element.

13. The applicator of Claim 1 wherein said core member is separable from said polymeric foam element.

14. The applicator of Claim 12 wherein said core member has a discontinuous surface which is operatively engagable with the foam of said polymeric foam element.

15. The applicator of Claim 14 wherein said surface includes a plurality of projections thereon.

16. The applicator of Claim 14 wherein said surface includes a plurality of depressions therein.

17. The applicator of Claim 14 wherein said surface includes a plurality of holes passing there through.

18. The applicator of Claim 1 wherein said core member has a substantially rounded distal end located within said polymeric foam element.

19. The applicator of Claim 1 including a handle portion extending outwardly from said polymeric foam element and being securely connected to said core member.

20. The applicator of Claim 19 wherein said handle portion and said core member are integrally formed.

21. The applicator of Claim 19 wherein said handle portion is substantially rigid.

22. The applicator of Claim 19 wherein said handle

portion is elongated and extends in substantial axial alignment with said polymeric foam element.

23. The applicator of Claim 19 wherein said handle portion is elongated and extends at an acute angle from the axis of said polymeric foam element.

24. The applicator of Claim 19 wherein said handle portion is substantially flexible.

25. The applicator of Claim 24 wherein said handle portion is adapted to be folded.

26. The applicator as claimed in Claim 25 further including means for retaining said handle portion in its folded position.

27. The applicator of Claim 1 further including an enlarged element adjacent the base of said polymeric foam element and extending transversely thereof.

28. The applicator of Claim 27 wherein said enlarged element is substantially leak proof.

29. The applicator of Claim 27 wherein said enlarged element is integral with said core member.

30. The applicator of Claim 27 wherein said enlarged element is integral with said polymeric foam element.

31. The applicator of Claim 27 wherein said enlarged element is substantially cup-shaped.

32. The applicator of Claim 27 further including a handle portion extending outwardly from said polymeric foam element and being securely connected to said core member, said enlarged element being in the form of a

flange located substantially at the junction between said handle portion and said polymeric foam element.

33. The applicator of Claim 32 wherein at least part of said flange is integral with said handle portion.

34. The applicator of Claim 32 wherein at least part of said flange is comprised of polymeric foam material.

35. The applicator of Claim 32 wherein said flange is constructed in two distinct parts each being comprised of different materials.

36. The applicator of Claim 35 wherein at least one of said materials is polymeric foam.

37. The applicator of Claim 35 wherein at least one of said parts is leak proof.

38. The applicator of Claim 32 wherein said handle portion is substantially flexible and is adapted to be folded and wherein said flange includes a means for retaining said handle portion in its folded position.

39. The applicator of Claim 1 wherein said core member is substantially hollow.

40. The applicator of Claim 39 further including a rod-shaped plunger element adapted to be slid into and out of said hollow core member.

41. The applicator of Claim 40 wherein said plunger includes a handle portion and a flange thereon adapted to limit movement of the plunger into said hollow core.

42. The applicator of Claim 39 further including a plurality of holes passing through the walls of said

hollow core member thereby allowing communication between the interior of said hollow core member and said polymeric foam element.

43. The applicator of Claim 42 wherein said core member includes a base adapted to be secured to the open end of a liquid container.

44. The applicator of Claim 43 wherein said base is adapted to be secured to the open end of a container with said polymeric foam element being located either in said container or extending outwardly away from said container.

45. The applicator of Claim 1 further including a recall loop secured to said core member and extending outwardly from said polymeric foam element.

46. The applicator of Claim 1 wherein the surface of said polymeric foam element includes a plurality of indentations therein.

47. The applicator of Claim 46 wherein said indentations are in the form of collecting troughs.

48. The applicator of Claim 1 wherein the surface of said polymeric foam element includes a plurality of scraping edges thereon.

49. The applicator of Claim 48 wherein said scraping edges are in the form of pliable fins.

50. The applicator of Claim 1 wherein at least part of said preselected medicament includes effervescent means.

51. The applicator of Claim 1 wherein at least part of said preselected medicament is encapsulated.

52. The applicator of Claim 1 wherein at least part of said preselected medicament includes means for time releasing the same.

53. The applicator of Claim 1 wherein at least part of said preselected medicament is released from said polymeric foam element by the action of internal body heat.

54. The applicator of Claim 1 wherein at least part of said preselected medicament is released from said polymeric foam element by the action of internal body fluids.

55. The applicator of Claim 1 wherein said polymeric foam element is highly hydrophilic.

56. The applicator of Claim 55 wherein said polymeric foam element is capable of absorbing up to 25 times its own dry weight of water.

57. The applicator of Claim 1 wherein the polymeric foam constituting the polymeric foam element is capable of being pre-impregnated by as much as 60 percent by weight of the desired medicament.

58. The applicator of Claim 1 wherein said polymeric foam element contains fibrous threads of polymeric material interwoven throughout the cellular matrix thereof.

59. The applicator of Claim 1 wherein said polymeric foam element has a densely structured cellular matrix of between approximately 6 to 30 lbs./ft.^{3}.

60. The applicator of Claim 1 wherein said polymeric foam element is comprised of normal and abnormal cells, said abnormal cells including ruptured, collapsed, distorted and swollen cells.

61. An applicator for treating a body cavity comprising:

a centrally located core member;

a polymeric foam element of predetermined shape substantially surrounding and being secured to said core member;

said foam element containing between 10 and 60 percent by weight of the foam an additive selected from a group consisting of medicaments, bactericides, antibiotics, germicides, fungicides, spermicides, soaps, detergents and emollients dispersed uniformly therein.

62. An applicator as claimed in Claim 61 wherein said foam element has a densely structured cellular matrix of between approximately 6 to 30 lbs./ft.^{3} and is comprised of normal and abnormal cells, said abnormal cells including ruptured, collapsed, distorted and swollen cells and further including fibrous threads of polymeric material interwoven throughout the cellular matrix thereof.

63. The applicator of Claim 61 wherein said polymeric foam element includes a smooth pliable skin surface.

64. The applicator of Claim 63 wherein said surface is porous.

65. The applicator of Claim 61 further including a soluble covering on at least part of the surface of said polymeric foam element.

66. The applicator of Claim 65 wherein said covering is integral with said polymeric foam element.

67. The applicator of Claim 65 wherein said covering is removable from said polymeric foam element.

68. The applicator of Claim 65 wherein said soluble covering includes a medicament therein.

69. The applicator of Claim 68 wherein the medicament contained in said soluble covering is different from the additive contained in said polymeric foam element.

70. The applicator of Claim 65 wherein said soluble covering is comprised of a plurality of layers.

71. The applicator of Claim 70 wherein at least one of said layers includes a medicament therein.

72. The applicator of Claim 70 wherein said plurality of layers are soluble at different rates of time.

73. The applicator of Claim 61 including a handle portion extending outwardly from said polymeric foam element and being securely connected to said core member.

74. The applicator of Claim 61 further including an enlarged element adjacent the base of said polymeric foam element and extending transversely thereof.

75. The applicator of Claim 74 wherein said enlarged element is substantially leak proof.

76. The applicator of Claim 61 wherein said core member is substantially hollow.

77. The applicator of Claim 76 further including a rod-shaped plunger element adapted to be slid into and out of said hollow core member.

78. The applicator of Claim 76 further including a plurality of holes passing through the walls of said hollow core member thereby allowing communication between the interior of said hollow core member and said polymeric foam element.

79. The applicator of Claim 78 wherein said core member includes a base adapted to be secured to the open end of a liquid container.

80. The applicator of Claim 79 wherein said base is adapted to be secured to the open end of a container with said polymeric foam element being located either in said container or extending outwardly away from said container.

81. The applicator of Claim 61 further including a recall loop secured to said core member and extending outwardly from said polymeric foam element.

82. The applicator of Claim 61 wherein the surface of said polymeric foam element includes a plurality of indentations therein.

83. The applicator of Claim 61 wherein the surface of said polymeric foam element includes a plurality of scraping edges thereon.

84. The applicator of Claim 61 wherein said polymeric foam element is highly hydrophilic.

85. The applicator of Claim 84 wherein said polymeric foam element is capable of absorbing up to 25 times its own dry weight of water.

86. A method of producing an applicator for treating a body cavity comprising the steps of:

mixing a polymeric foamable material to obtain a partial polymerized mass;

adding a predetermined additive to said mass, said additive being selected from the group consisting of medicaments, bactericides, antibiotics, germicides, fungicides, spermicides, soaps, detergents and emollients;

mixing said combined mass and additive to

substantially evenly disperse said additive;

pouring the mixture into a mold and forming the same into a predetermined shape.

87. The method of Claim 86 including the step of positioning a support structure in said mold to be joined with said polymeric material.

88. The method of Claim 86 further including the step of minimizing foaming during said second mixing step.

89. The method of Claim 88 wherein said foaming is minimized by dispersing evolved gases.

90. The method of Claim 86 including the step of encapsulating said additive prior to adding the same to said mass.

91. The method of Claim 86 including the step of coating the outer surface of the polymeric material formed in said mold with a soluble coating material.

92. The method of Claim 91 wherein said soluble coating includes a medicament therein.

93. The method of Claim 91 wherein said coating step includes the step of lining the mold walls with said coating material.

94. The method of Claim 91 wherein said coating step includes the step of preforming a soluble sheath and sliding said sheath over said outer surface.

95. The method of Claim 86 wherein said first mixing step includes mixing a prepolymer urethane resin with a catalyst at 500 to 2500 RPM for 30 to 100 seconds.

96. The method of Claim 95 wherein said second mixing step includes mixing said combined mass and additive at 250 to 1000 RPM for 15 to 100 seconds.

97. The method of Claim 86 wherein said second mixing step includes mixing said combined mass and additive at 250 to 1000 RPM for 15 to 100 seconds.

Fig. 1

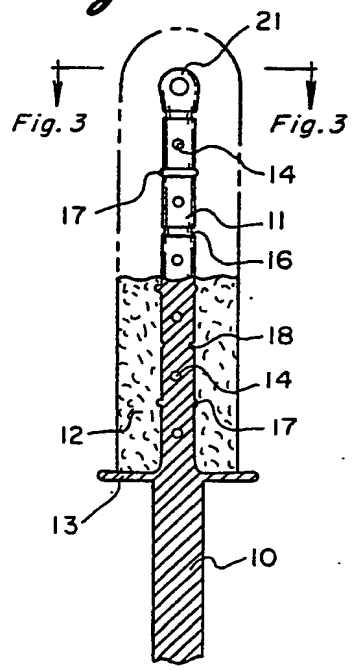


Fig. 2

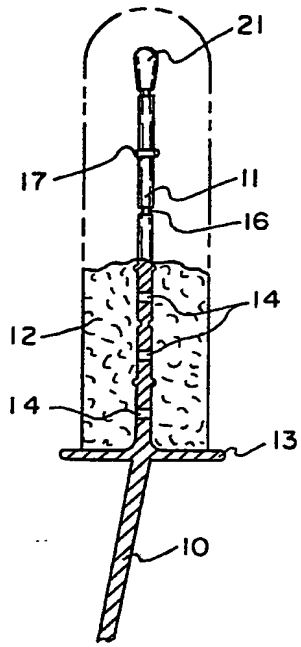


Fig. 3

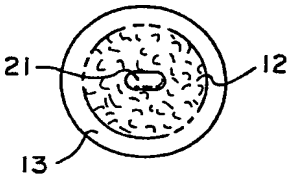


Fig. 4

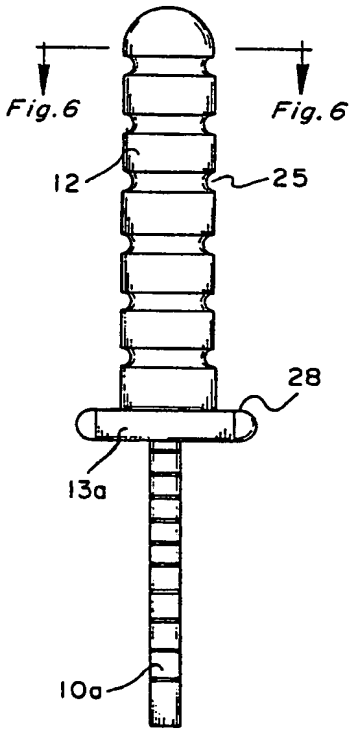


Fig. 6

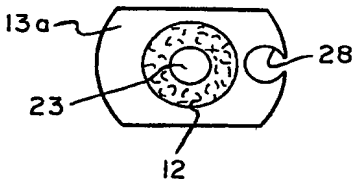


Fig. 5

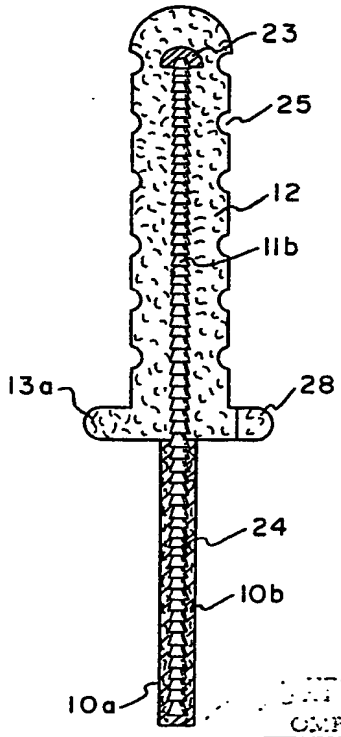


Fig. 7

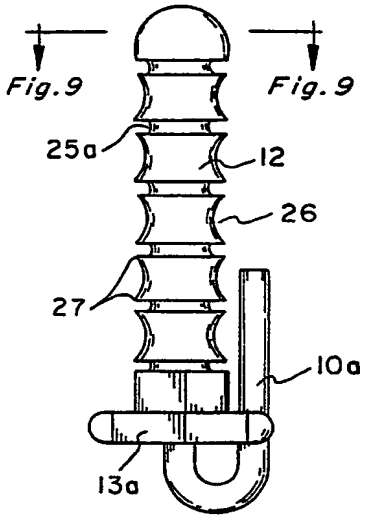


Fig. 8

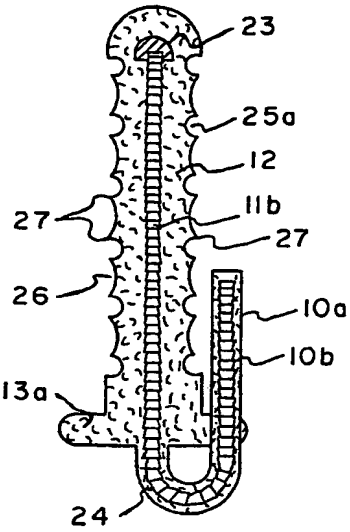


Fig. 9

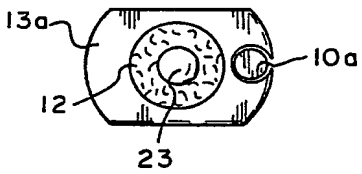
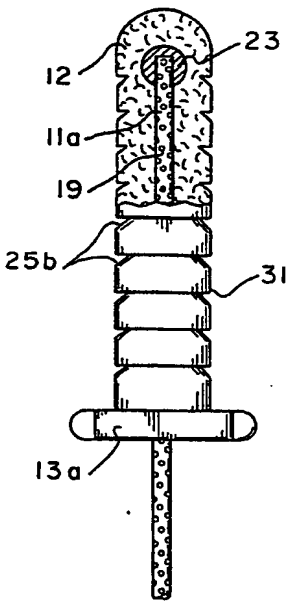


Fig. 10



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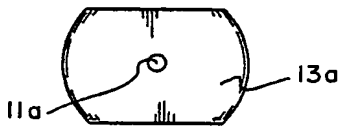

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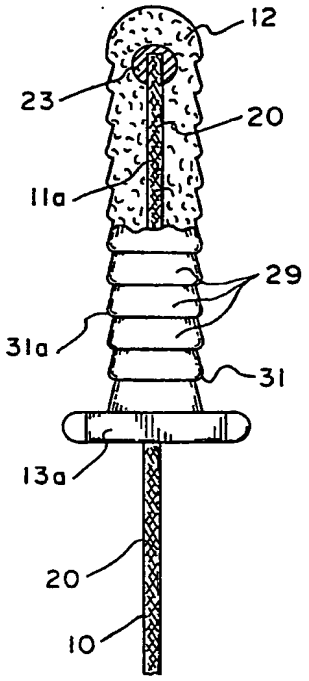


Fig. 13

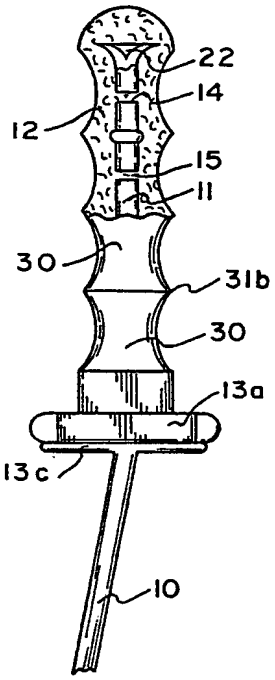


Fig. 14

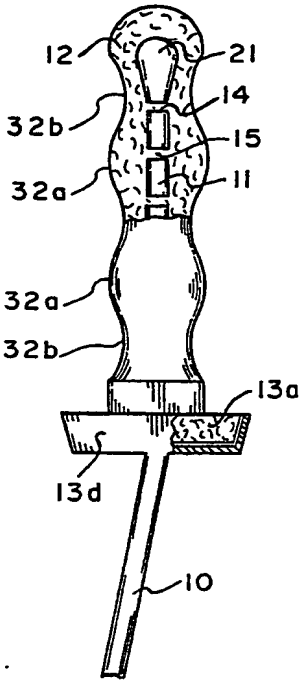


Fig. 15

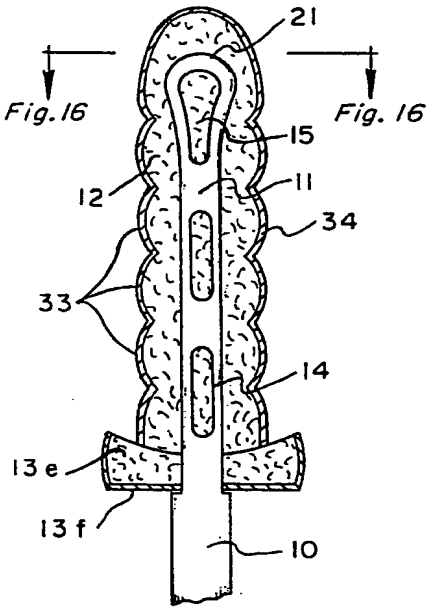


Fig. 16

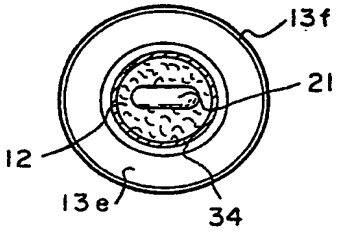


Fig. 17

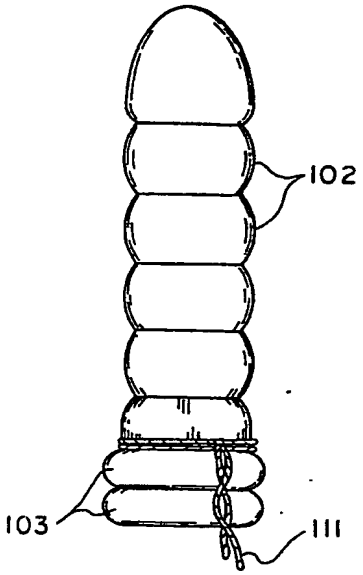


Fig. 18

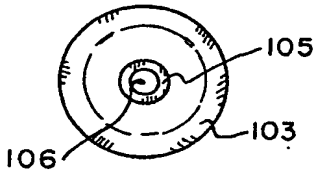


Fig. 19

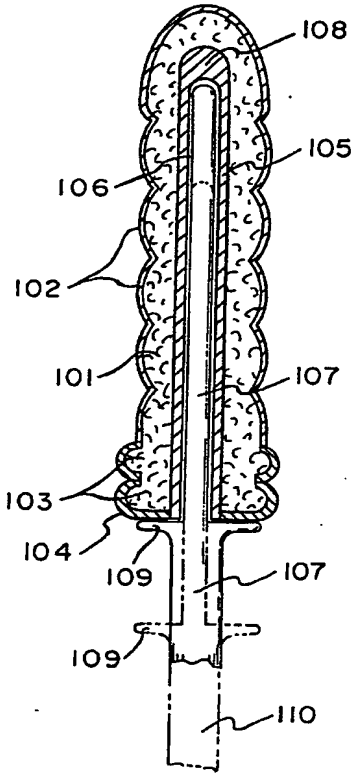


Fig. 20

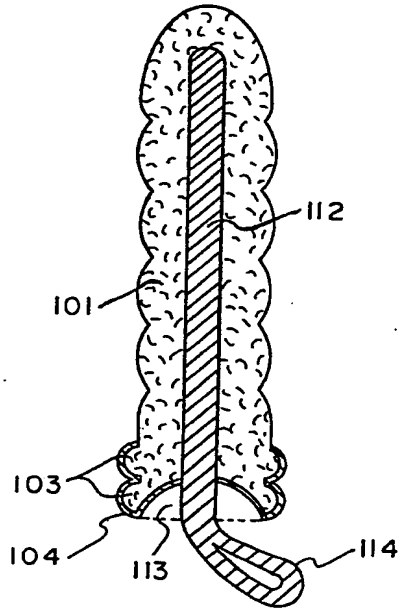


Fig. 21

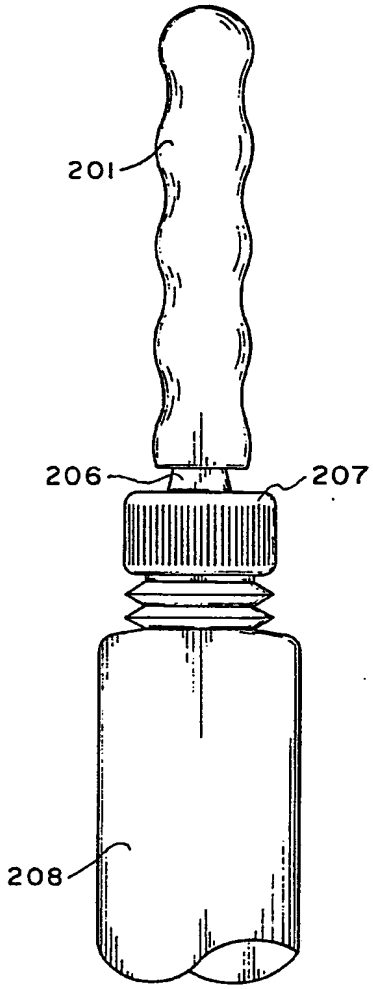


Fig. 22

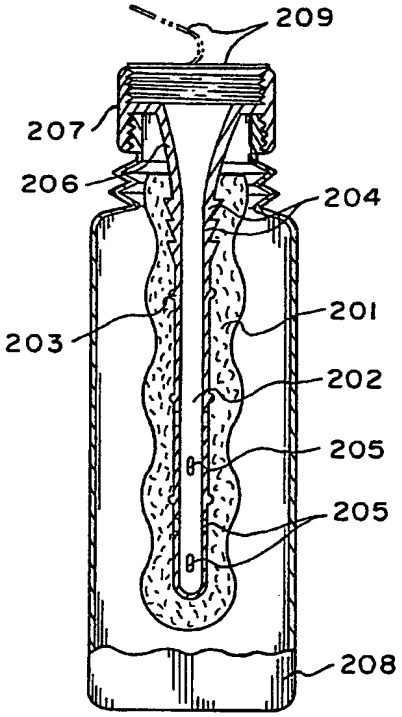


Fig. 23

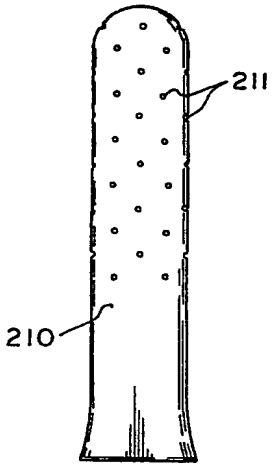


Fig. 24

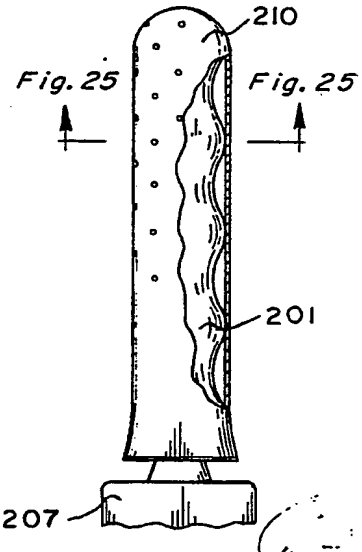


Fig. 25

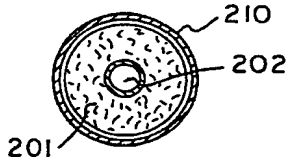


Fig. 26

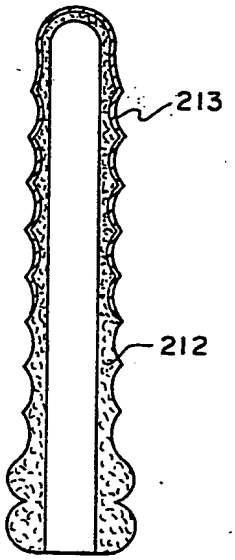


Fig. 28

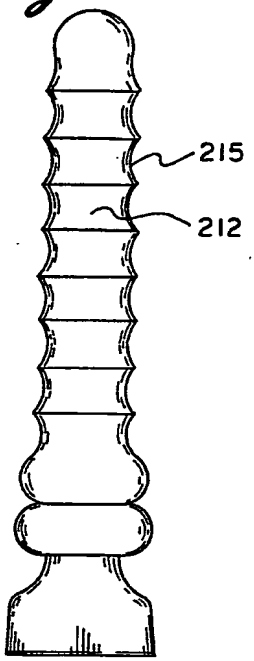


Fig. 27

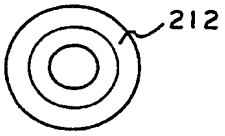


Fig. 29

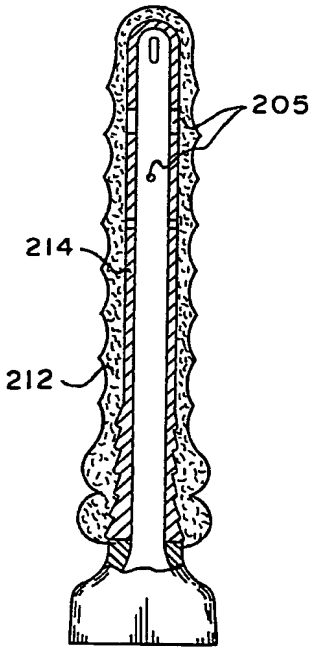
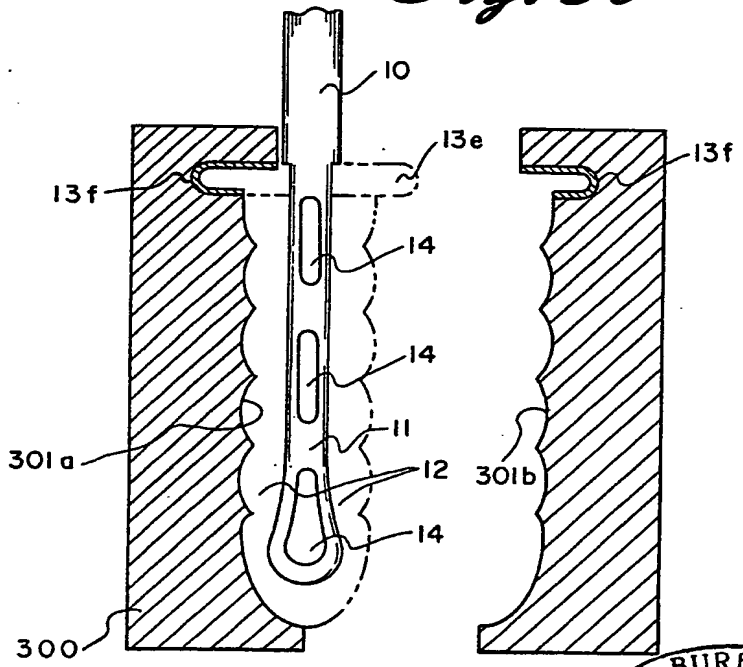


Fig. 30



INTERNATIONAL SEARCH REPORT

International Application No PCT/US80/01030

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[3] A61M 7/00
U.S. Cl. 128/260

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/260,267,269,67,127 ,264/46.6

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US,A, 3,818,911, Published June 25, 1974 FOURNIER	1-97
X	US,A, 3,343,540, Published September 26, 1967 SIEGEL	1-97
X	US,A, 3,389,418, Published June 25, 1968 SENCABAUGH	16,17
A	US,A, 3,813,462, Published May 28, 1974 ROBERTS	86-97
A	US,A, 3,985,951, Published October 12, 1976 HARRIS	86-97
A	JP,A, 49-66762, Published August 26, 1972 NIPA	86-97

* Special categories of cited documents: [15]

"A" document defining the general state of the art
"E" earlier document but published on or after the international filing date
"L" document cited for special reason other than those referred to in the other categories
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but on or after the priority date claimed
"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention
"X" document of particular relevance

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
December 10, 1980	24 DEC 1980
International Searching Authority [1]	**Signature of Authorized Officer [20]**
U.S.	R. Michell

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers_____, because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers_____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-85, drawn to an applicator.
Claims 86-97 drawn to a method of molding an applicator.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.